

Claims

characterised in that it comprises a

~~an effective dose of~~ Pharmaceutical composition comprising a synergistic combination of inulin and an anti-metabolic anti-cancer drug.

2. Pharmaceutical composition according to claim 1 wherein the inulin is inulin with a DP up to about 100, or oligofructose or a mixture thereof.

3. Pharmaceutical composition according to claim 1 or claim 2, wherein the inulin is chicory inulin with a ( $\overline{DP}$ ) ranging from about 10 to about 30, or oligofructose with a DP ranging from 2 to 7 and containing about 5 wt% in total of glucose, fructose and sucrose.

4. Pharmaceutical composition according to any one of claims 1 to 3 wherein the anti-cancer drug is selected from the group consisting of methotrexate, cytarabin, fluorouracil, mercaptopurin, thioguanine, azathioprine and hydroxycarbamide.

5. Pharmaceutical composition according to claim 4 wherein the anti-cancer drug is 5-fluorouracil or methotrexate.

6. Pharmaceutical composition according to any one of claims 1 to 5 which additionally to the said anti-metabolic anti-cancer drug contains one or more anti-cancer drugs belonging to the class of anti-metabolic anti-cancer drugs and/or to another class of anti-cancer drugs.

7. Pharmaceutical composition according to any one of claims 1 to 6 in which the inulin and the anti-metabolic anti-cancer drug which constitute the synergistic combination are simultaneously present in the same galenic formulation.

8. Pharmaceutical composition according to any one of claims 1 to 6 in which the inulin and the anti-metabolic anti-cancer drug which constitute the synergistic combination are present in separate formulations which together form the pharmaceutical composition.

9. Pharmaceutical composition according to any one of claims 1 to 8 wherein the single galenic formulation or the separate galenic formulations forming the pharmaceutical composition are suitable for oral, parenteral or rectal administration, or for tube feeding.

10. Pharmaceutical composition according to claim 8 in which the inulin is present in a functional food or feed.

11. Pharmaceutical composition according to claim 8 in which the anti-cancer drug is present in a formulation which is suitable for oral or parenteral administration.

WO 99/59600

PCT/EP99/03399

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12. Pharmaceutical composition according to any one of claims 1 to 11 for use as a medicament for the treatment of cancer in humans.
13. Pharmaceutical composition according to any one of claims 1 to 11 for use as a medicament for the treatment of cancer in non-ruminating mammals.
- 5        14. Use of a combination of inulin and an anti-metabolic anti-cancer drug for the manufacture of a pharmaceutical composition as defined in any one of claims 1 to 11 for the treatment of cancer in humans or in a non-ruminating mammal.
- 10      15. Method for the treatment of cancer in a human or in a non-ruminating mammal comprising administering to said being in need of such treatment an effective amount of a pharmaceutical composition as defined in any one of claims 1 to 11.
- 15      16. Method according to claim 15 wherein the inulin and the anti-metabolic anti-cancer drug of the synergistic combination forming the pharmaceutical composition are present in the same galenic formulation constituting the pharmaceutical composition.
- 20      17. Method according to claim 15 wherein the inulin and the anti-metabolic anti-cancer drug of the synergistic combination forming the pharmaceutical composition are present in separate galenic formulations constituting together the pharmaceutical composition.
- 25      18. Method according to claim 17 wherein the separate galenic formulations are administered simultaneously or non-simultaneously.
19. Method according to claim 17 wherein the separate galenic formulations are administered via different methods of administration and the inulin is administered by a method selected from the group consisting of oral, parenteral or rectal administration and administration via tube feeding.
- 30      20. Method according to claim 19 wherein the separate galenic formulation containing the inulin is a functional food or feed.

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